

Memorandum of Meeting

Date: August 24, 2001

Site: 1350 Piccard Dr., Rockville, MD 20850

Firm: Sartorius, Inc., 131 Heartland Dr., Edgewood, NY 11717

Participants, Sartorius, Inc:

Dr. Oscar-Werner Reif, Director, Research and Development

Ms. Denise E. Schettino, Product Manager, Bioprocess

Mr. Juergen van den Boogaard, Technical Coordinator

Dr. Reinhard Baumfalk, Head of Test Systems Development

Participants, FDA:

Charles Ahn, Consumer Safety Officer, Office of Regulatory Affairs, Office of Regional Operations

Tom M. Chin, CSO, ORA, Office of Enforcement

Rick Friedman, CSO, Center for Drug Evaluation and Research, Div. Med. Product Quality

Mark Hackman, CSO, Center for Food Safety and Applied Nutrition, Office of Field Programs

Paul Motise, CSO, ORA, Office of Enforcement

Charles Snipes, Compliance Officer, CDER, Div. of Scientific Investigations

The meeting was convened at the request of Sartorius, Inc., to discuss the firm's approach to access and electronic record keeping system features used in an apparatus to determine filter integrity.

The visitors were advised that discussions at this meeting may not be construed as FDA endorsement of the design, use of the product, or the product complies with the regulations.

The visitors described the system and controls for system administration, user accounts, restricting access, closed system conditions, setting test parameters, secured time stamped audit trails for electronic records within the firm's stand alone device (not for files stored externally to the device), electronic signature display, reporting, providing FDA with suitable electronic copies of electronic records, method in use to ensure copy accuracy, and retention of test result electronic records.

The visitors did not distribute any handouts.

Prepared by: Tom M. Chin

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FDA Attendees

Part 11 Dockets:

Validation 00D-1538

Glossary 00D-1543

Archiving 00D-1539

Time stamps 00D-1542

E-copies 00D-1540

Audit trails 00D-1541

HFC-230 (r/f, chron, File: Electronic Records-Electronic Signatures)

HFA-224

Draft: Tchin: SartoriusMOM.doc

Edit: Pmotise 8/30/2001; Tchin 9/20/2001

Final: Tchin 9/20/2001

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